(12) UK Patent (19) GB (11) 2 422 114 (13) B

(45) Date of publication: **16.04.2008**

(54) Title of the invention: Extra-aortic patch

(51) INT CL: ***A61M 1/12*** (2006.01)

(21) Application No: **0607080.9**

(22) Date of Filing: **28.10.2004**

(30) Priority Data:
(31) **2003905993** (32) **30.10.2003** (33) **AU**

(86) International Application Data:
PCT/AU2004/001483 En 28.10.2004

(87) International Publication Data:
WO2005/042063 En 12.05.2005

(43) Date A Publication: **19.07.2006**

(56) Documents Cited:
WO 2002/024255 A1 **WO 2002/024254 A1**
WO 2000/076288 A2
Patent Abstracts or Japan JP10-328297

(58) Field of Search:
As for published application 2422114 A *viz:*
INT CL **A61B**, **A61F**, **A61M**
Other
updated as appropriate

Additional Fields
Other
ONLINE:EPODOC, WPI

(72) Inventor(s):
William Suttle Peters

(73) Proprietor(s):
Sunshine Heart Company Pty Ltd
(Incorporated in Australia)
2A River Street, Birchgrove,
New South Wales 2095, Australia

(74) Agent and/or Address for Service:
fJ Cleveland
40-43 Chancery Lane, LONDON,
WC2A 1JQ, United Kingdom

EXTRA-AORTIC PATCH

Field of the Invention

The present invention relates generally to a counter-pulsation heart assist device, system and method and, more particularly, to an extra-aortic patch and a heart assist device and method using aortic deformation.

Background of the Invention

The Applicant's International PCT Patent Application Nos. PCT/AU00/00654 and PCT/AU02/00974 disclose various counter-pulsation heart assist devices that utilise aortic deformation. The contents of these specifications are hereby incorporated herein by cross reference.

Known counter-pulsation heart assist devices generally include an inelastic shell with a flexible membrane sealingly attached to the periphery of the shell. The membrane defines an inflatable space between it and the interior of the shell. The shell also has an inlet/outlet port which is adapted for connection to a motive means that can periodically introduce, and withdraw, a fluid to and from the space in counter-pulsation with the patient's heart rhythm. A substantially inelastic, flexible wrap is placed around an arterial vessel and over the device to secure the device adjacent the exterior of the vessel. The balloon is normally positioned on the radially outer side of the ascending aorta.

It is the object of the present invention to provide an alternative means for securing a heart assist device adjacent an arterial vessel.

Summary of the Invention

Accordingly, in a first aspect, the present invention provides a heart assist device adapted for securing to an arterial vessel, the heart assist device including an inflatable balloon or chamber, wherein:

the balloon or chamber is directly attachable to the exterior of the arterial vessel.

Preferably the balloon or chamber does not extend around the complete circumference of the arterial vessel.

A second aspect of the present invention provides a heart assist device adapted for securing to an arterial vessel, the heart assist device including an inflatable balloon or chamber and a shroud wherein the shroud is directly attachable to the exterior of the arterial vessel.

The shroud periphery is preferably suturable to the vessel. The sutures are preferably non-absorbable. If the balloon is positioned over the descending thoracic aorta, the shroud periphery is sutured to the intercostal fascia and fascia overlying the vertebral column.

In another form, the shroud periphery is adapted for gluing to the vessel.

As a further alternative, the shroud periphery is adapted for stapling or clipping to the vessel.

The shroud may be directly attachable to the arterial vessel with the inflatable balloon or chamber secured beneath the shroud and adjacent the exterior of the arterial vessel.

Brief Description of the Drawings

A preferred embodiment of the invention will now be described, by way of an example only, with reference to the accompanying drawings in which:

Fig. 1 is a schematic perspective view of an aorta of a patient with a first embodiment of a device according to the invention attached thereto;

Fig. 2 is a schematic cross section view of the aorta and device shown in Fig. 1 along line 2-2; and

Fig. 3 is a schematic cross section view of an aorta and a second embodiment of device according to the invention attached thereto.

Detailed Description of the Preferred Embodiments

Fig. 1 is a schematic perspective view of an ascending aorta 10 and a heart assist device 12 according to a first embodiment of the invention. The device 12 has a fluid tube 14 for connection to a motive power source (not shown), which sealingly engages a bushing 16. A flexible balloon membrane 18 (see Fig. 2) is sealingly attached to the bushing 16. The balloon 18 is formed from a polyurethane, polyurethane-silicone co-polymer, silicone, or similar material

The balloon 18 is protected by an inelastic, shroud 20, which snugly engages the bushing 16 and sealingly sandwiches the open end of the balloon 18 therebetween. The shroud 20 has a larger peripheral extent (ie. is wider) than the balloon 18. The balloon 18 defines an inflatable space 22. The shroud 20 can be formed in part of whole of polyurethane, polyurethane-silicone co-polymer, silicone, polyester, or similar materials.

The device 12 is secured on the radially outer side of the ascending aorta 10 by the shroud 20 being directly attached to the aorta 10 by one or two rows of non absorbable sutures 24 along the sides of the shroud 20. The sutures 24 are preferably of the mono-filament type, such as Prolene 3/0 (Trade Mark), but may be any nonabsorbable material.

In operation, the motive means periodically introduces, and withdraws, a fluid (e.g. a gas such as helium or air or a liquid such as a saline solution or an oil) to and from the space 22 in counter-pulsation with the patient's heart rhythm. When fluid is introduced into the space 22, the balloon 18 expands and the aorta's external wall is compressed and inwardly deformed until it is close to but not abutting the aorta's opposite interior wall. When fluid is withdrawn from the space 22, the balloon retracts to the

configuration shown in Fig. 2 and the aorta 10 returns to normal position allowing maximum blood flow therethrough.

Fig. 3 is a schematic cross-sectional view of an ascending aorta 10 and a heart assist device 30 according to a second embodiment of the invention. Like features to those of the first embodiment will be denoted with like reference numerals in relation to the second embodiment. The device 30 differs from the device 12 in that the balloon 18 is itself directly attached to the aorta 10 by glue at (darkened) region 32.

The advantages of the above devices include that they are relatively easier and safer to implant compared to known surgical procedures because they are not in the blood stream, and because the ascending aorta does not need to be completely mobilised free of the pulmonary artery. The second embodiment also allows for placement of aorto-coronary bypass grafts to the ascending aorta, separate from the device 30. Additionally, as the back part of the aorta is not attached to the device, the ascending aorta retains a majority of its anisotropic elastic nature which is important to minimise any loss of aortic compliance. Such devices may be particularly useful in patients having re-do surgery, where scar tissue may make complete mobilisation of the aorta from the pulmonary artery difficult. Additionally, redo patients may have patent aorto-coronary bypass grafts, that can be retained on the aorta. The devices described above also allows for growth and/or dilation of the aorta over time and as such may be suitable for use in younger patients where the aorta is smaller, more elastic and growing, or in patients who have been in severe heart failure and the ascending aorta is smaller than normal for any given age, due to chronically low cardiac output. The advantages of such a device and method on the descending aorta is that, due to presence of multiple side-branches, circumferential wrapping is not easily achieved, and "patch" attachment is more achievable. Further, with the descending thoracic aorta, a longer length is made available and thus a larger balloon can be used. Finally, the devices described above advantageously reduce the amount of foreign material introduced into a patient's body.

It would be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiment without departing from the spirit or scope of the invention as broadly described. For example, surgical glue could be used in place of the sutures.

CLAIMS

1. A heart assist device adapted for securing to an arterial vessel, the heart assist device including an inflatable balloon or chamber, wherein:

the balloon or chamber is directly attachable to the exterior of the arterial vessel.

2. A device as claimed in claim 1, wherein the balloon or chamber does not extend around the complete circumference of the exterior of the arterial vessel.

3. A device is claimed in claim 1 or claim 2, wherein the inflatable balloon or chamber is directly attachable to the arterial vessel by gluing.

4. A device as claimed in claim 3, wherein the inflatable balloon or chamber is directly attachable the arterial vessel using an associated fibrin or another natural protein.

5. A heart assist device adapted for securing to an arterial vessel, the heart assist device including an inflatable balloon or chamber and a shroud wherein the shroud is directly attachable to the exterior of the arterial vessel.

6. A device is claimed in claim 5, wherein the shroud is directly attachable to the arterial vessel by one or more of suturing, gluing, stapling or clipping to the arterial vessel.

7. A device as claimed in claim 6, wherein the shroud has a periphery and substantially all of the shroud periphery is suturable to the intercostal fascia and fascia overlaying the vertebral column.

8. A device as claimed in any one of claims 5 to 7, wherein the shroud is directly attachable to the arterial vessel with the inflatable balloon or chamber secured beneath the shroud or wrap and adjacent exterior of the arterial vessel.

9. A device as claimed in any one of claims 5 to 8, wherein the shroud does not extend around the complete circumference of the exterior of the arterial vessel.

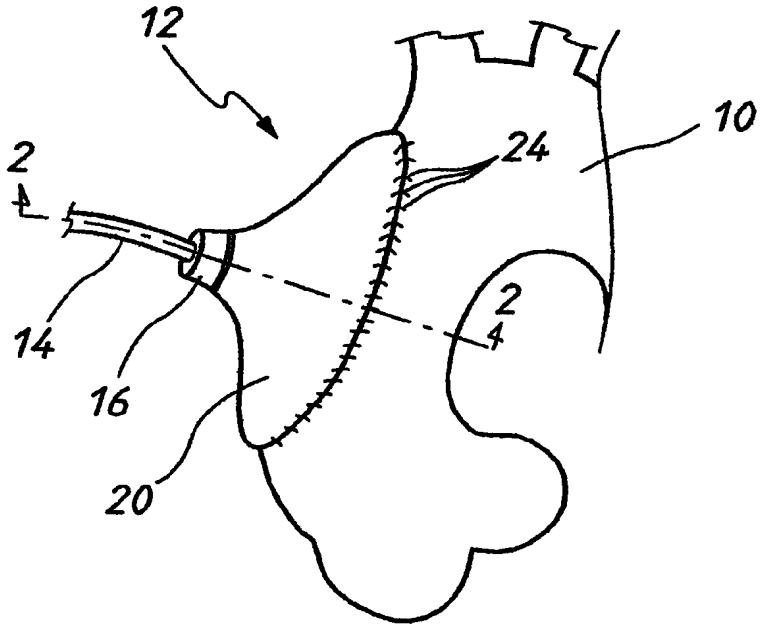

FIG. 1

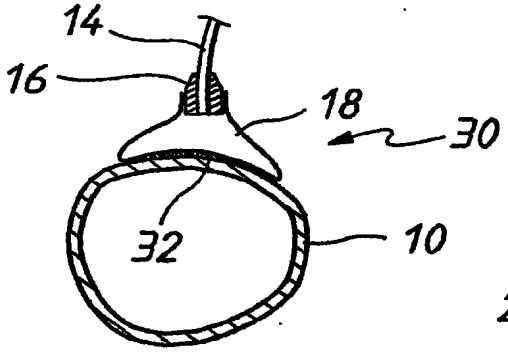

FIG. 3

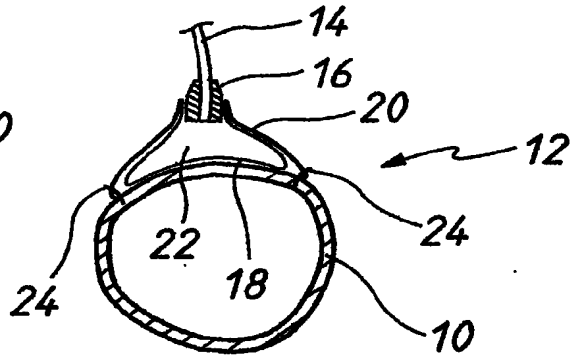

FIG. 2